

are used, the indication may be limited to: “Use [in bold type] helps prevent, protect, and relieve chapped lips”.

(iii) The “external use only” warning in § 347.50(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The warnings in § 347.50(c)(2), (c)(3), and (c)(4) are not required.

(iv) The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vi) of this chapter may be omitted, provided the information after the heading “Warning” contains the warning in § 347.50(e)(1)(iii).

(v) The warnings in § 201.66(c)(5)(x) of this chapter may be omitted.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(1), (c)(3), (c)(6), and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

(f) *Products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), singly or in combination with each other, and marketed other than as a lip protectant.* (1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), and (c)(5) may be presented as follows:

(i) The active ingredients (§ 201.66(c)(2) of this chapter) shall be listed in alphabetical order.

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to “Use [in bold type] helps protect minor cuts and burns” or “Use [in bold type] helps” (optional: “prevent and”) “protect chapped skin” or “Use [in bold type] helps protect minor cuts and burns and” (optional: “prevent and protect”) “chapped skin”.

(iii) The warning in § 347.50(c)(3) may be revised to read “See a doctor if condition lasts more than 7 days.”

(iv) The subheadings in § 201.66(c)(5)(iv) through (c)(5)(vii) of this chapter may be omitted, provided the information after the heading “Warnings” contains the warnings in § 347.50(c)(2), (c)(4), and (f)(1)(iii).

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(3) and (c)(7) may be omitted.

[68 FR 33377, June 4, 2003, as amended at 68 FR 68511, Dec. 9, 2003; 73 FR 6017, Feb. 1, 2008]

#### § 347.52 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “astringent.” *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b),* under the “Purpose” heading identified in § 201.66(c)(3) of this chapter, the labeling of each active ingredient in the product states “Astringent\*”, which is followed by the statements “\* When combined together in water, these ingredients form the active ingredient aluminum acetate. See [the following in bold italic type] Directions.”

(b) *Indications.* The labeling of the product states, under the heading “Uses” any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition of section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b).* “For temporary relief of minor skin irritations due to: [select one or more of the following: ‘poison ivy,’ ‘poison oak,’ ‘poison sumac,’ ‘insect bites,’ ‘athlete’s foot,’ or ‘rashes caused by soaps, detergents, cosmetics, or jewelry’].”

(2) *For products containing aluminum sulfate identified in § 347.12(b) for use as a*

*styptic pencil*. “Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving.”

(3) *For products containing witch hazel identified in § 347.12(c)*. “Relieves minor skin irritations due to: [select one or more of the following: ‘insect bites,’ ‘minor cuts,’ or ‘minor scrapes’].” [If more than one condition is used, each is preceded by a bullet.]

(c) *Warnings*. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *For all products*—(i) The labeling states “For external use only”.

(ii) The labeling states “When using this product [bullet] avoid contact with eyes. If contact occurs, rinse thoroughly with water.”

(2) *For products containing aluminum acetate identified in § 347.12(a), witch hazel identified in § 347.12(c), or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*. The labeling states “Stop use and ask a doctor if [bullet] condition worsens or symptoms last more than 7 days”.

(3) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a compress or wet dressing*. The labeling states “When using this product [bullet] do not cover compress or wet dressing with plastic to prevent evaporation”.

(4) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a soak, compress, or wet dressing*. The labeling states “When using this product [bullet] in some skin conditions, soaking too long may overdry”.

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For products used as a soak*. “For use as a soak: [preceding words in bold type]

[bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use”.

(ii) *For products used as a compress or wet dressing*. “For use as a compress or wet dressing: [preceding words in bold type] [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use”.

(2) *For products containing aluminum sulfate identified in § 347.12(b) for use as a styptic pencil*. “Moisten tip of pencil with water and apply to the affected area. Dry pencil after use.”

(3) *For products containing witch hazel identified in § 347.12(c)*. “Apply as often as needed”.

(4) *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For powder dosage form*. The labeling states “[bullet] dissolve 1 to 3 packets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 packet), [insert percent] (2 packets), or [insert percent] (3 packets) aluminum acetate and is ready for use.” These statements shall be the first statements under the heading “Directions”.

(ii) *For tablet dosage form*. The labeling states “[bullet] dissolve 1 to 3 tablets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 tablet), [insert percent] (2 tablets), or [insert percent] (3 tablets) aluminum acetate and is ready for use.” These statements shall be the first statements under the heading “Directions”.

(e) *Products formulated and labeled as a styptic pencil and that meet the criteria established in § 201.66(d)(10) of this chapter*. The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter

except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(4) and (c)(5) may be presented as follows:

(i) The heading and indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] stops bleeding of minor cuts from shaving”.

(ii) The “external use only” warning in § 347.52(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The second warning in § 347.52(c)(1) may state: “avoid contact with eyes”. The warning in § 201.66(c)(5)(x) may be limited to the following: “Keep out of reach of children.” The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) may be omitted, provided the information after the heading “Warning” contains the warnings in this paragraph.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(3) and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

[68 FR 33377, June 4, 2003, as amended at 68 FR 35293, June 13, 2003; 69 FR 3005, Jan. 22, 2004; 74 FR 9765, Mar. 6, 2009]

#### § 347.60 Labeling of permitted combinations of active ingredients.

The statement of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of iden-

tity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading “Uses,” the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. In addition to the required information identified in this paragraph (b), the labeling of the product may contain any of the “other allowable statements” that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) *Combinations of skin protectant and external analgesic active ingredients in § 347.20(b).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), any or all of the allowable indications for external analgesic drug products may be used if the product is labeled for concurrent symptoms.

(2) *Combinations of skin protectant and first aid antiseptic active ingredients in § 347.20(c).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), the required indications for first aid antiseptic drug products should be used.

(3) *Combinations of skin protectant and sunscreen active ingredients in § 347.20(d).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(2)(i), the required indications for sunscreen drug products